

(b) Requests for information regarding blood establishment registrations and blood product listings should be directed to the Department of Health and Human Services, Food and Drug Administration, Office of Compliance, Center for Biologics Evaluation and Research (HFB-100), 8800 Rockville Pike, Bethesda, MD 20892.

[40 FR 52788, Nov. 12, 1975, as amended at 49 FR 23833, June 8, 1984; 55 FR 11014, Mar. 26, 1990]

§ 607.39 Misbranding by reference to establishment registration or to registration number.

Registration of an establishment or assignment of a registration number or assignment of a NDC number does not in any way denote approval of the firm or its products. Any representation that creates an impression of official approval because of establishment registration or possession of registration number or NDC number is misleading and constitutes misbranding.

Subpart C—Procedures for Foreign Blood Product Establishments

§ 607.40 Blood product listing requirements for foreign blood product establishments.

(a) Every foreign establishment shall comply with the blood product listing requirements contained in Subpart B of this part, unless exempt under Subpart D of this part, whether or not it is also registered.

(b) No blood product may be imported from a foreign establishment into the United States except a blood product imported or offered for import pursuant to the investigational use provisions of part 312 of this chapter, unless it is first the subject of a blood product listing as required in Subpart B of this part. The blood product listing information shall be in the English language.

(c) Foreign establishments shall submit, as part of the blood product listing, the name and address of the establishment and the name of the individual responsible for submitting blood product listing information. Any changes in this information shall be reported to the Food and Drug Administration at the intervals specified for

updating blood product listing information in § 607.30(a).

[40 FR 52788, Nov. 12, 1975, as amended at 55 FR 11014, Mar. 26, 1990]

Subpart D—Exemptions

§ 607.65 Exemptions for blood product establishments.

The following classes of persons are exempt from registration and blood product listing in accordance with this part 607 under the provisions of section 510(g) (1), (2), and (3) of the act, or because the Commissioner has found, under section 510(g)(4), that such registration is not necessary for the protection of the public health.

(a) Pharmacies that are operating under applicable local laws regulating dispensing of prescription drugs and that are not manufacturing blood products for sale other than in the regular course of the practice of the profession of pharmacy including the business of dispensing and selling blood products at retail. The supplying by such pharmacies of blood products to a practitioner licensed to administer such blood products for his use in the course of his professional practice or to other pharmacies to meet temporary inventory shortages are not acts which require such pharmacies to register.

(b) Practitioners who are licensed by law to prescribe or administer drugs and who manufacture blood products solely for use in the course of their professional practice.

(c) Persons who manufacture blood products which are not for sale, rather, are solely for use in research, teaching, or analysis, including laboratory samples.

(d) Carriers, by reason of their receipt, carriage, holding, or delivery of blood products in the usual course of business as carriers.

(e) Persons who engage solely in the manufacture of in vitro diagnostic blood products and reagents not subject to licensing under section 351 of the Public Health Service Act (42 U.S.C. 262). This paragraph does not exempt such persons from registration and listing for medical devices required under part 807 of this chapter.

(f) Transfusion services which are a part of a facility approved for Medicare

reimbursement and engaged in the compatibility testing and transfusion of blood and blood components, but which neither routinely collect nor process blood and blood components. The collection and processing of blood and blood components in an emergency situation as determined by a responsible person and documented in writing, therapeutic collection of blood or plasma, the preparation of recovered human plasma for further manufacturing use, or preparation of red blood cells for transfusion are not acts requiring such transfusion services to register.

(g) Clinical laboratories that are approved for Medicare reimbursement and are engaged in the testing of blood products in support of other registered blood establishments.

[40 FR 52788, Nov. 12, 1975, as amended at 43 FR 37997, Aug. 25, 1978; 45 FR 85729, Dec. 30, 1980; 49 FR 34449, Aug. 31, 1984]

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

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- 610.63 Divided manufacturing responsibility to be shown.
- 610.64 Name of selling agent or distributor.
- 610.65 Products for export.

AUTHORITY: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

SOURCE: 38 FR 32056, Nov. 20, 1973, unless otherwise noted.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see parts 124 and 125 of the Domestic Mail Manual, that is incorporated by reference in 39 CFR part 111.

Subpart A—Release Requirements

§ 610.1 Tests prior to release required for each lot.

No lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product. Each applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies. The results of all tests performed shall be considered in determining whether or not the test results meet the test objective, except that a test result may be disregarded when it is established that the test is invalid due to causes unrelated to the product.